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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,204	12/21/2001	George L. King	10276-066001	1396

26161 7590 08/07/2003

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BOSTON, MA 02110

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,204

Applicant(s)

King

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-6, 16-38, and 40-43 is/are pending in the application.
- 4a) Of the above, claim(s) 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, and 16-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment received 4/9/2003 has been entered and claims 1, 2, 4-6, 16-38, 40-43 are currently pending in this application.

5 In view of the amendments to the claims and arguments presented, the rejections of record under 35 USC 112, first and second paragraphs, are hereby withdrawn.

10 Newly submitted claims 40-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are directed to evaluating the relative age of a subject which is a distinct and independent invention from those originally claimed.

15 Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

20 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-2, 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ceolotto.

10 Ceolotto (Diabetes) entitled ~~Protein Kinase C Activity is~~
Acutely regulated by Plasma Glucose Concentration in Human
Monocytes In Vivo ~~teaches~~ teaches on page 1316 column 2, assessing PKC
in monocytes may mirror that of vascular cells, the relation
between hyperglycemia and PKC activity. On page 1318 column 2,
monocytes are a useful model to detect hyperglycemia induced
changes in PKC protein content and activity. PKC activity in
15 monocytes may parallel those in other types of cells such as
vascular cells. Glucose induced alteration in monocyte PKC
kinase activity may be relevant to the study of development of
diabetic complications and atherosclerosis.

20 All the features of the claims are taught by Ceolotto for
the same function as claimed.

Applicant's arguments filed 4/9/2003 have been fully
considered but they are not persuasive.

25 Applicant argues that Ceolotto describes a correlation
between monocyte PKC activity and blood glucose, nothing more.
The other suggestions of Ceolotto are merely speculation.

It is the examiner's position that Ceolotto clearly teaches PKC activity in monocytes may parallel those in other types of vascular cells as related to diabetic complications.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be

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negated by the manner in which the invention was made.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ceolotto.

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Ceolotto (Diabetes) entitled ~~Protein~~ Protein Kinase C Activity is Acutely regulated by Plasma Glucose Concentration in Human Monocytes In Vivo~~teaches~~ teaches on page 1316 column 2, assessing PKC in monocytes may mirror that of vascular cells, the relation between hyperglycemia and PKC activity. On page 1318 column 2, monocytes are a useful model to detect hyperglycemia induced

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changes in PKC protein content and activity. PKC activity in monocytes may parallel those in other types of cells such as vascular cells. Glucose induced alteration in monocyte PKC kinase activity may be relevant to the study of development of diabetic complications and atherosclerosis.

Claims 16-22 differ from Ceolotto in that they specify evaluating the extent, stage, or severity of a cardiovascular complication of diabetes. Claims 23-29 differ in that they are directed to determining the efficacy of treating, claims 30-37 are directed to identifying a compound for treating, and claim 38 is directed to identifying a compound for treating aging.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to diagnose, treat, evaluate treating, identify compounds to treat a disorder after comprehending the mechanism of action of the disorder. Ceolotto discloses a relation between PKC activity in monocytes and hyperglycemic disorders and sequelae. The leap from altering PKC activity to then altering hyperglycemic disorders and sequelae would have been obvious because most presently treated disorders followed the same pattern. For example, once it was understood certain bacteria caused infections, to then alter those bacteria, diagnose infections, treat infections, evaluate the treating and identify compounds to treat followed. No unexpected results are disclosed. Regarding aging, there are so many conditions, disorders and diseases that may be associated with aging, including diabetic complications, that it would be encompassed by Ceolotto.

Applicant's arguments filed 4/9/2003 have been fully considered but they are not persuasive.

Applicant argues that Ceolotto describes a correlation between monocyte PKC activity and blood glucose, nothing more. Ceolotto does not suggest a correlation between monocyte PKC activity and cardiovascular complications of diabetes. The subjects of the study were free of retinopathy or renal impairment. No diagnostic correlation is seen. Ceolotto does not mention aging.

It is the examiner's position that Ceolotto discusses the relevance of the study to diabetic complications generally and atherosclerosis specifically. Retinopathy and nephropathy are well known complications of diabetes. Aging is such a broad term that it encompasses the claimed disorders at least.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the
5 statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner
10 can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for this Art Unit are before
15 final (703) 872-9306 and after final (703) 872-9307. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing
20 applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

Ralph Gitomer

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Primary Examiner
Group 1651

RALPH GITOMER
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